


























This document specifies symbols used on **BÜHLMANN Products**, according to ISO 15223-1:2021:







Symbol	Title	Description and Requirements
	Manufacturer	Indicates the medical device manufacturer. This symbol shall be accompanied by the name and address of the manufacturer adjacent to the symbol.
	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union. This symbol shall be accompanied by the name and address of the authorized representative, adjacent to the symbol.
	Date of manufacture	Indicates the date when the medical device was manufactured. This symbol shall be accompanied by a date to indicate the date of manufacture.
	Use-by date	Indicates the date after which the medical device is not to be used. This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified. This symbol shall be accompanied by the manufacturer's batch code adjacent to the symbol.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified. This symbol shall be accompanied by the manufacturer's catalogue number adjacent to the symbol.







Symbol	Title	Description and Requirements
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified. This symbol shall be accompanied by the manufacturer's serial number adjacent to the symbol.
	Importer	Indicates the entity importing the medical device into the locale. This symbol shall be accompanied by the name and address of the importing entity adjacent to the symbol.
	Distributor	Indicates the entity distributing the medical device into the locale. This symbol shall be accompanied by the name and address of the distributing entity adjacent to the symbol.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbols is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Symbol	Title	Description and Requirements
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed. The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.
	Do not re-use	Indicates a medical device that is intended for one single use only.
	<i>In vitro</i> diagnostic medical device	Indicates a medical device that is intended to be used as an <i>in vitro</i> diagnostic medical device.
	Contains sufficient for <n> tests	Indicates the total number of tests that can be performed with the medical device. The number of tests that can be performed with the medical device shall appear adjacent to the symbol.
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information. This symbol may be used when multiple data carriers are present on the label. If used, this symbol shall be placed adjacent to the unique device identifier carrier.
	For IVD Performance evaluation only	Indicates an <i>in vitro</i> diagnostic medical device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.

## Additional symbols used (not covered by ISO 15223-1:2021):

Symbol	Title	Description
	CE marking	<p><b>CE</b> marking means a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulation (EU) 2017/746 and Richtlinie 98/79/EG and other applicable Union harmonisation legislation providing for its affixing.</p> <p>Regulation (EU) 2017/746; Richtlinie 98/79/EG</p>
	CE marking with four-digit identification number of NB	<p>A <b>CE</b> marking followed by a four-digit identification number indicates that a Notified Body (NB) was involved in conformity assessment.</p> <p><b>CE0123</b> shows that TÜV SÜD was the Notified Body involved in conformity assessment.</p> <p>Regulation (EU) 2017/746; Richtlinie 98/79/EG</p>
	Restricted devices in US	<p>Indicates a medical device that can only be sold, distributed or used upon the order of an authorized healthcare provider in the USA.</p> <p>21 CFR 801.109(b)(1)</p>
	Health Industry Bar Code System	<p>The HIBC (Health Industry Bar Code) is a worldwide system that contains the Unique Device Identifier (UDI) embedded in a 2D/Matrix bar code. The Unique Device Identification (UDI) system is used for uniform product labelling of medical devices and allows to trace medical devices quickly and easily from the manufacturer to the user.</p> <p>Regulation (EU) 2017/746</p>
	For near-patient testing	<p>Indicates that the device is only to be used in a near patient setting by a health professional.</p> <p>A 'near patient test' is not to be used by the patient themselves.</p>
	Not for near-patient testing	<p>Indicates that the device (applies to rapid tests only) is <u>not</u> intended for near-patient testing.</p> <p>A rapid test with this symbol on its label should only be used by a trained laboratory professional in a laboratory. This symbol should be put on rapid tests that are intended for exclusive use in a laboratory environment.</p>

Symbol	Title	Description
	For self-testing	Indicates that the device is a self-test <i>in vitro</i> diagnostic device. This means that a lay person can use it even without formal healthcare or medical experience.
	Not for self-testing	Indicates that the device (applies to rapid tests only) is not intended for self-testing. A rapid test with this symbol should only be used by a trained medical or a lab professional in an appropriate setting.
	UDI Device Identifier	The UDI Device Identifier (UDI-DI) is a unique numeric or alphanumeric code specific to a model of device and that is also used as the 'access key' to information stored in a UDI database. Regulation (EU) 2017/746
	Ingress Protection	The first numeral ( <b>X</b> ) refers to the protection against solid objects and is rated on a scale from 0 (no protection) to 6 (no ingress of dust). The second numeral ( <b>Y</b> ) rates the enclosure's protection against liquids and uses a scale from 0 (no protection) to 9 (high-pressure hot water from different angles). IEC 60529:1989
	Crossed-out wheeled bin	Indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. Directive 2012/19/EU; IEC 60417
	This way up	Indicates the correct upright position of a transport package. ISO 7000

Symbol	Title	Description
	Direct current	Indicates that the equipment is suitable for direct current only; to identify relevant terminals. IEC 60417
	Internet Vector Icon	Icon used as a synonym for "Click here to go the website or Internet".
	IBDoc® mobile app	Icon representing the application icon of the IBDoc® mobile app.
	QR code containing „download“ icon	The QR code containing the "download" icon is a synonym for "Scan the QR code with your smartphone to download the mobile application".
	App Store	Icon indicating that the mobile application is available for download on the App Store.
	Google Play Store	Icon indicating that the mobile application is available for download on the Google Play Store.